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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,656	03/03/1999	MARC PETERS-GOLDEN	UM-03662	2349

7590

05/07/2002

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/07/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/291,656

Applicant(s)

PETERS-GOLDEN ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-25 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-25 and 27-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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This Office Action is in response to Paper #11, filed February 6, 2002. Claims 1-21 and 26 have been canceled. Claims 22-25 and 27-37 are currently pending and are under examination.

Withdrawal of Rejections

The rejection of Claims 22- 32 under 35 U.S.C. 102(e) as being anticipated by Gosselin et al. (USP 5,789,441; priority to February 15, 1996) is withdrawn.

New Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 28-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Gosselin et al. (USP 5,789,441; priority to February 15, 1996). Gosselin et al. teach leukotriene LTB₄ in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example). The term "LTB₄" includes leukotrienes C₄, D₄, and E₄ (col. 6, line 52). Therefore, a solution comprising a sterile liquid and a leukotriene (Claims 22, 26, 27, 28, 32), wherein the leukotriene is LTB₄ (Claims 23, 29), or wherein the leukotriene is a cysteinyl leukotriene (Claim 24, 30) such as leukotrienes C₄, D₄, and E₄ (Claims 25, 31) is taught by Gosselin et al.

While the claims recite that the solution is in an endotracheal tube, a bronchoscope, or a nebulizer, for example, these phrases are given no patentable weight. See *Union Oil Co. of*

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California v. Atlantic Richfield Co., 54 USPQ2d 1227, *In re Rosicky*, 125 USPQ 341; *In re Riden et al.*, 138 USPQ 112; *In re Lerner* 169 USPQ 51. Therefore, the Claims are anticipated by Gosselin et al. as set forth above.

Claims 22, 23, 27, 33, 34, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Imai et al. (1990; Jpn J. Allergol 39(10): 1380-1387). Imai et al. teach leukotriene B4 as in aerosol generated from a nebulizer, for the administration to dogs. Therefore, an aerosol of leukotriene B4 in a sterile liquid vehicle that is aerosolized (Claims 22, 23, 27) is taught by Imai et al. This solution was placed into a nebulizer (Claims 33, 34, 37).

Claims 22, 24, 25, 27, 33, 35, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimura et al. (1991; Prostaglandins 42(4):379-389). Fujimura et al. teach the administration via inhalation of leukotriene C4 from a nebulizer to guinea pigs. Therefore, an aerosol of leukotriene C4 in a sterile liquid vehicle that is aerosolized (Claims 22, 24, 25, 27) is taught by Fujimura et al. This solution was placed into a nebulizer (Claims 33, 35, 36, 37).

Claims 22, 24, 25, 27, 33, 35, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ball et al. (1991; J. Pharmacol. Methods 26(3):187-202). Ball et al. teach the administration via inhalation of leukotriene D4 from a nebulizer to guinea pigs. Therefore, an aerosol of leukotriene D4 in a sterile liquid vehicle that is aerosolized (Claims 22, 24, 25, 27) is taught by Ball et al. This solution was placed into a nebulizer (Claims 33, 35, 36, 37).

Claims 22, 24, 25, 27, 33, 35, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al. (1984; Agents Actions 14(1): 43-48). O'Donnell et al. teach the administration via inhalation of leukotriene E4 from a nebulizer to guinea pigs. Therefore, an

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aerosol of leukotriene E4 in a sterile liquid vehicle that is aerosolized (Claims 22, 24, 25, 27) is taught by O'Donnell et al. This solution was placed into a nebulizer (Claims 33, 35, 36, 37).

Claims 28, 29, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. 1989; J. Clin Invest. 84:1609-1619). Martin et al. teach leukotriene B4 in a sterile solution in a bronchoscope – see page 1610, col. 1, para. 1.

Claims 28, 29, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwama et al. J. Pharm. Pharmacol. 45(4):286-291). Iwama et al. teach leukotriene B4 in a sterile solution that is administered by intra-tracheal injection. Therefore, this solution was placed into an endotracheal tube.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

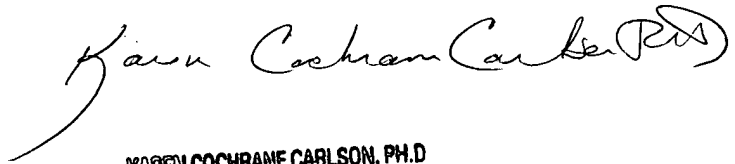
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:30 AM - 5:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

May 1, 2002


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER